Appl. No. : **10/706,346**
Filed : **November 12, 2003**

REMARKS

Claims 1, 3-6, 8-17, and 21 were pending before the Examiner. Claims 15-17 were withdrawn by Examiner as drawn to a non-elected species. The Examiner considered Claims 1, 3-6, 8-14, and 21. In this paper, Applicants have canceled Claims 22-85 and added new Claims 86-106. New Claims 99-103 depend from previously-withdrawn Claim 7. No claims are amended herein. Thus, Claims 1, 3-6, 8-14, 21, 86-98, and 104-106 are now before the Examiner. No new matter has been added with these amendments.

The present application discloses various embodiments of a percutaneous cannula for directing blood into a vessel of a patient. The cannula initially may be applied to a vessel in a reduced profile configuration, wherein the cannula can be more easily inserted percutaneously into the patient's vasculature. In one non-limiting embodiment, depicted below in a slightly modified version of Figure 23A from the application, the cannula includes a proximal end, a main cannula portion, a tip portion, a distal end, and a lumen extending between the proximal end and the distal end. The main cannula portion extends distally from the proximal end of the cannula. The lumen extends through the main cannula portion and conveys blood in one application. The tip portion is configured to direct blood-flow in a direction generally opposite of the direction of flow through the lumen. The tip portion can include a redirecting member. The redirecting member can be arranged to expand to uncover discharge openings under the pressure in the lumen of the cannula. The redirecting member also can be collapsible to cover the discharge openings during insertion of the cannula. In the below illustration, bolded lines have been added to Figure 23A as filed to depict an approximate flow path of blood through the tip portion of the cannula.

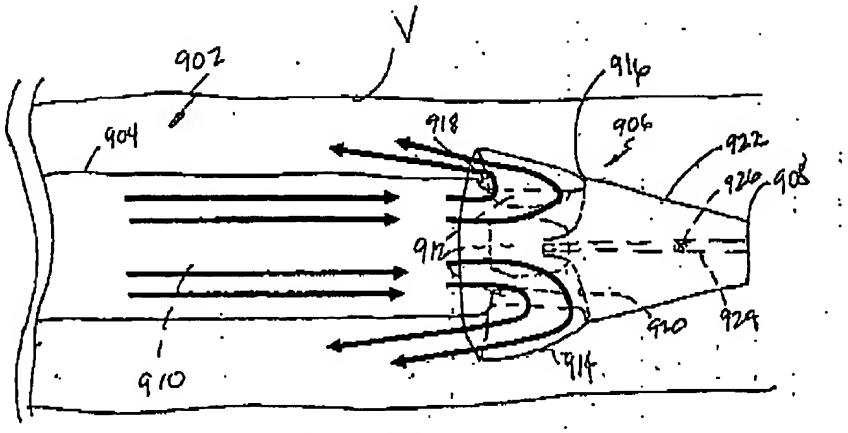

Fig. 25A

(Present application, lines added to depict blood flow path)

Rejections Based on Prior Art

The Examiner rejected Claims 1, 3-6, 8, and 21 under 35 U.S.C. § 102(b) over U.S. Patent No. 6,293,958 to Berry et al. Examiner also rejected Claims 9-14 under 35 U.S.C. § 103(a) as unpatentable over Berry in view of U.S. Patent Application Publication No. 2003/0040736 to Stevens et al. For the reasons discussed below, Applicants respectfully traverse these rejections.

Berry

As depicted below in Figure 1, Berry discloses a catheter having a flow diffusing distal tip. The tip includes a plurality of cuts formed through the tubular wall thereof so as to define a plurality of generally U-shaped flaps. The U-shaped flaps are hinged along one edge to diffuse contrast fluid injected therethrough. In particular, when contrast fluid is injected under pressure into the proximal end of the catheter, the fluid exits the openings in which the plurality of flaps are hinged, causing the flaps to vibrate. The vibration of the flaps reduces the tendency of the contrast media to be expelled as a jet from the open distal end of the catheter.

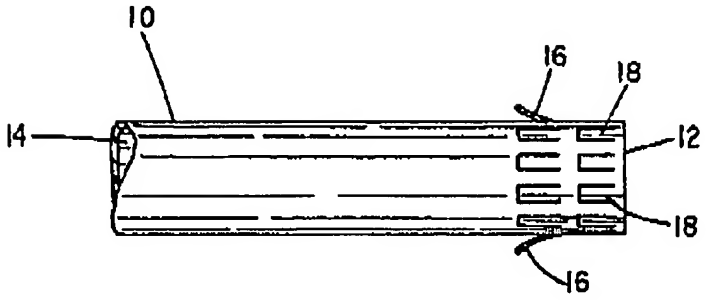

FIG. 1

(**Berry et al**, U.S. Patent No. 6,293,958)

Berry Does Not Anticipate Claim 1

Claim 1 of the present application recites, *inter alia*, "a redirecting member comprising an expandable member configured to expand under the pressure of blood flow directed through the discharge opening." In contrast, Berry discloses a plurality of cut "U-shaped hinged flaps" positioned in a flow-diffusing distal tip of a catheter. (Berry, Col. 3: ll 7-8). A flow of fluid through the catheter results in the hinged flaps tending to "deform through the three-sided opening defined by the cuts and enter the space occupied by the lumen." (Col. 3: ll 12-15). The flaps tend to oscillate, moving into and out of the lumen about their hinged ends. (Col. 3: ll 15-22). The hinged flaps disclosed by Berry do not "expand" as is recited with respect to the expandable member of Claim 1. Nor does Berry indicate that the flaps are somehow "expandable" or "configured to expand." Rather, Berry merely discloses that the flaps are formed by a series of three sided cuts in the walls of a catheter, the catheter being of a "flexible plastic." (Col. 2: ll 53-55; Col. 3: ll 5-9). With the exception of localized material flex at the hinge end, the flaps disclosed by Berry maintain a constant geometry that is merely pivoted to diffuse fluid flow.

The Berry catheter is intended to be "used to inject a contrast media into a target coronary blood vessel." (Col. 2: ll 51-52). The oscillating flap structure disclosed by Berry is intended to create a "confused, turbulent broken flow" in this contrast media. (Col. 3: ll 53-54). If the Berry catheter were used for blood supplementation, as Applicants intend their invention, the turbulent flow induced by the Berry catheter would create local disturbances and flow eddies in blood

flow. These flow abnormalities would tend to form harmful and potentially deadly blood clots. Therefore, Berry does not disclose a blood flow lumen, an expandable member configured to expand under the pressure of the blood flow, or a redirecting member configured to direct blood flow, all of which are recited in Claim 1 of the present application. Claims 3-6, 8, and 21 depend from Claim 1 and recite additional limitations thereon. These dependent claims are allowable for at least the reasons disclosed above with respect to Claim 1.

Claims 9-14 Are Not Obvious in View of the Combination of Berry and Stevens

The Stevens et al publication discloses a cardiac venting catheter and system for withdrawing blood and other fluids from a patient's heart. The Examiner indicated that Berry fails to disclose a pump and additional lumens as recited in Claims 9-14 of the present application but that Stevens discloses these features. For at least the reason that the combination of Berry and Stevens suggested by Examiner fails to disclose all of the elements recited in any of Claims 9-14, Applicants respectfully traverse this rejection.

Claims 9-14 each depend from Claim 1, and neither Stevens nor Berry discloses "a redirecting member comprising an expandable member configured to expand under the pressure of blood flow directed through the discharge opening" as is recited in Claim 1. As discussed above with respect to the rejection of Claim 1, Berry fails to disclose the recited expandable member. While Stevens does disclose various catheters and systems for use in cardiac venting, Stevens contributes nothing to the disclosure of Berry with respect to the expandable member recited in Claim 1. Therefore, because neither Berry nor Stevens recite all of the limitations of Claims 9-14, Applicants respectfully submit that these claims are patentably distinct from the combination of references cited by Examiner.

Because neither Berry nor Stevens disclose the recited expandable member, Applicants have not addressed the limitations of Claims 9-14 asserted by Examiner to be disclosed by Stevens. Further, Applicants have not addressed the propriety of combining Stevens with Berry as suggested by Examiner. However, this lack of discussion should not be interpreted as an admission by Applicants concerning the disclosure of Stevens or the propriety of the combination of Berry with Stevens. Applicants reserve these issues for later argument.

Withdrawn Claims

Claim 7 and 15-20 have been withdrawn from consideration. However, as discussed above, Claim 1 is believed to be allowable and is generic at least to at least two withdrawn species. For example, Claim 1 is generic to Species J (identified in the *Restriction Requirement* mailed March 13, 2006), e.g., as recited in Claim 7. Claim 1 also is generic to the subject matter of withdrawn Claims 15-17 and to withdrawn Species H, e.g., as recited in Claims 18-20. Therefore, as provided by 37 CFR §1.141, Applicants request that all the claims directed to the withdrawn species be examined and allowed.

New Claims 86-106 Are In Condition For Allowance

Applicants have added new Claims 86-106 depending from Claim 1 and further defining the invention thereof. Claims 86-98 and 104-106 correspond to the elected species, i.e. Species G as defined in the *Restriction Requirement* mailed March 13, 2006. Claims 86-98 and 104-106 depend from Claim 1 and are patentable for at least the reasons discussed above with respect to Claim 1. Therefore, Applicant requests that Claims 86-98 and 104-106 be examined and allowed.

New Claims 99-103 depend from previously-withdrawn Claim 7 and correspond to Species J as defined in the *Restriction Requirement* mailed March 13, 2006. These claims further define the invention and do not add new matter. As provided by 37 CFR §1.141, Applicant requests that Claims 99-103 be examined and allowed.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance and respectfully request that a Notice of Allowance be issued at the earliest opportunity. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 24, 2006

By: _____
Andrew M. Douglas
Registration No. 51,212
Attorney of Record
Customer No. 20,995
(949) 760-0404

2582509